APR 1 0 2002

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
MAHURKAR® Triple Lumen Catheter

Section H – 510(K) Summary

K020089

Date Summary Was Prepared: January 9, 2002

Submitter's Information:
The Kendall Company
Division of Tyco Healthcare Group, LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000
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Contact:
Regina Yeh
Senior Specialist, Regulatory Affairs
The Kendall Company
Division of Tyco Healthcare Group, LP
Telephone: 508-261-8404
Fax: 508-261-8461

Device Trade Name: MAHURKAR® Triple Lumen Catheter for Hemodialysis, Apheresis, and Infusion

Device Common Name: Catheter, Hemodialysis, Non-implanted

Classification Panel: Gastroenterology

Legally Marketed Devices To Which Substantial Equivalence Is Claimed To: The MAHURKAR® Triple Lumen Catheter is substantially equivalent to MAHURKAR® Triple Lumen Catheter for Infusion with respect to its design, materials, and physical characteristics, and MAHURKAR® Dual Lumen Catheter with respect to its intended use and performance characteristics.

Device Description: The MAHURKAR® Triple Lumen Catheter features three lumens. The catheter has a 12 Fr radiopaque polyurethane catheter shaft with two large lumens and one smaller medial lumen running longitudinally along the length of the catheter shaft. The lumina can be distinguished by the color-coded luer-lock adapters on the clear silicone rubber extensions. The two large lumens have curved extensions, and the smaller medial lumen has straight extension tubing. The catheter is available in various implantable lengths.

MAHURKAR® Triple Lumen Catheter is available in singles, kit or tray configuration which contains the sterile catheter as well as accessory items needed for insertion.

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Intended Use: MAHURKAR® Triple Lumen Catheter is intended for short-term central venous access for hemodialysis, apheresis, and infusion.

Performance Data: Performance data for MAHURKAR® Triple Lumen Catheter were compared to that of the predicate devices identified in this 510(K) summary. These test results demonstrate that the proposed device is substantially equivalent to the legally marketed predicate devices.

Clinical Summary

In a multi-centered, prospective, randomized clinical study, 485 patients underwent an infection evaluation, based on a comparison between the MAHURKAR® Triple Lumen Catheter and the MAHURKAR® Dual Lumen Catheter. Patients received either acute hemodialysis or apheresis treatments were randomized to receive either the proposed or the predicate device. Performance data, treatment outcomes and complications were collected during these procedures. The primary outcome of this study is whether there was a catheter related blood stream infection for each patient at the time of catheter removal.

Based on 393 evaluable patients studied, multivariate logistic regression analysis was performed to compare the infection rate of the two devices. The results show that the infection rate was 7.5% for the MAHURKAR® Triple Lumen Catheter and 8.3% for the MAHURKAR® Dual Lumen Catheter. The MAHURKAR® Triple Lumen Catheter infection rate was thus regarded as acceptable as there was no indication that the infection rates of the two catheters were different (P = 0.77 by the Chi-square test).

Regina S. Yeh
Senior Regulatory Affairs Specialist
The Kendall Company

1/9/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2002

Ms. Regina S. Yeh
Sr. Regulatory Affairs Specialist
The Kendall Company
Division Tyco Healthcare Group, LP
15 Hampshire Street
MANSFIELD MA 02048

Re: K020089
Trade/Device Name: MAHURKAR® Triple Lumen Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 NIE
Dated: January 9, 2002
Received: January 10, 2002

Dear Ms. Yeh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit and tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit and tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device tray contains 1% Lidocaine, which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Device Name:

Mahurkar® Triple Lumen Catheter

Indications for Use:

Mahurkar® Triple Lumen Catheter is intended for short-term central venous access for hemodialysis, apheresis, and infusion.

Please Do Not Write Below This Line – Continue On Another Page If Needed

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020089